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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/856,376	05/14/1997	MARK CHEE	16528X-02501	2915

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EXAMINER

ZHOU, SHUBO

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 08/856,376	<b>Applicant(s)</b> CHEE ET AL.	
	<b>Examiner</b> Shubo (Joe) Zhou	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,15-32 and 34-71 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,15-32,34,51-53,70 and 71 is/are rejected.
- 7) ☒ Claim(s) 35-50 and 54-69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/3/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's amendment and request for reconsideration filed 6/5/06 are acknowledged and amendments entered.

Claims 1, 3-10, 15-32 and 34-71 are currently pending and under consideration.

#### ***Withdrawn Rejections***

The rejection of Claims 1, 3, 17, and 20 under 35 U.S.C. 102(a) and (e)(2) as being anticipated by Wallace (P/N 5,494,794) set forth in the previous Office action mailed 8/1/05 is hereby withdrawn in view of the amendment to the claims.

#### ***Information Disclosure Statement***

The Information Disclosure Statement filed 11/3/05 has been entered and documents listed therein have been considered. Initialed copies of the form PTO-1449 are enclosed with this action.

#### ***Claim Rejections-35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3 and 15-32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are directed to a DNA molecule which has the same characteristics as DNA found naturally and therefore does not constitute patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-naturally occurring products does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However, when purity results in new utility, patentability is considered. Merck Co. v. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fier Disintegrating Co., 90 USPQ 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed product is suggested to obviate this rejection. For example, “An isolated segment...” is suggested.

#### ***Claim Rejections-35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-10, 15, 31-32, 34, 51-53 and 70-71 are rejected under 35 U.S.C. § 102(b) as being anticipated by Stoneking et al. (Am. J. Hum. Genet. Vol. 48, pages 370-380, 1991).

Claims 1, 15 and 31-32 are drawn to a segment of human mitochondrial DNA including “a polymorphic site” shown in Table 1 selected from a group of polymorphic sites. A polymorphic site is interpreted as being a particular site or position in the DNA molecule where a polymorphism is present. However, it does not require a particular nucleotide.

Stoneking et al. disclose a series of population variations of the human mtDNA. Such variations are interpreted as polymorphism. Stoneking et al. disclose a plurality of mtDNA polymorphic sites or positions including polymorphic sites at 93 (as in claim 15), 16111 (as in claim 31), 16145 (as in claim 32), etc. See Fig. 2 on page 372 and legend thereof on page 373.

These sites are numbered according to the method of Anderson et al. 1981, which method is also used to number the polymorphic sites in the instant application. See page 8.

Claim 3 is drawn to particular polymorphic sites wherein they are occupied by a particular nucleotide. The polymorphic sites disclosed by Stoneking et al. include site 195 wherein it is occupied by "C", which is the same as that listed in column 4 of Table 1 of the instant application and which is other than that listed in column 3, i.e. "t" of Table 1.

Claims 4-8 are drawn to an allele specific oligonucleotide comprising a particular polymorphic site that is occupied by a particular nucleotide that is the same as that disclosed in Table 1, column 1 but other than the base shown in Table 1 column 3.

Stoneking et al. disclose an allele specific oligonucleotide comprising a "G" at 73. The allele specific oligonucleotide is used as a probe and primer. See page 374, Table 1.

Claims 9, 53 and 70-71 are drawn to an isolated nucleic acid comprising a particular nucleotide at a particular position.

Stoneking et al. disclose a nucleic acid generated by PCR that comprises polymorphic sites of the human mtDNA.

With regard to claim 9, the polymorphic sites disclosed by Stoneking et al. include site 195 wherein it is occupied by "C", which is the same as that listed in column 4 of Table 1 of the instant application and which is other than that listed in column 3, i.e. "t" of Table 1.

With regard to claim 53, the polymorphic sites disclosed by Stoneking et al. include site 64 wherein it is occupied by "T" (see #19 at the leftmost column), which is the same as that listed in column 6 of Table 1 of the instant application and which is other than that listed in column 3, i.e. "c" of Table 1.

With regard to claim 70, the polymorphic sites disclosed by Stoneking et al. include site 16111 wherein it is occupied by "T" (see #50 at the leftmost column), which is the same as that

listed in column 2 of Table 1 of the instant application and which is other than that listed in column 3, i.e. “c” of Table 1.

With regard to claim 71, the polymorphic sites disclosed by Stoneking et al. include site 16145 wherein it is occupied by “A” (see #31 at the leftmost column), which is the same as that listed in column 9 of Table 1 of the instant application and which is other than that listed in column 3, i.e. “g” of Table 1.

Claims 10, 34 and 51-52 are drawn to a method of analyzing a nucleic acid comprising obtaining the nucleic acid from an individual and identifying a base occupying a polymorphic site. Stoneking et al. disclose a method comprising generating a nucleic acid by PCR from an individual and identifying a polymorphic site.

With regard to claims 10 and 34, the polymorphic sites disclosed by Stoneking et al. include site 64 wherein it is occupied by “T” (see #19 at the leftmost column), which is the same as that listed in column 6 of Table 1 of the instant application and which is other than that listed in column 3, i.e. “c” of Table 1.

With regard to claim 51, the polymorphic sites disclosed by Stoneking et al. include site 16111 wherein it is occupied by “T” (see #50 at the leftmost column), which is the same as that listed in column 2 of Table 1 of the instant application and which is other than that listed in column 3, i.e. “c” of Table 1.

With regard to claim 52, the polymorphic sites disclosed by Stoneking et al. include site 16145 wherein it is occupied by “A” (see #31 at the leftmost column), which is the same as that listed in column 9 of Table 1 of the instant application and which is other than that listed in column 3, i.e. “g” of Table 1.

### ***Claim Objections***

Claims 35-50 and 54-69 are objected to as being dependent from a rejected claim.

*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.  
Patent Examiner

